Regulatory correspondence log **EXHIBIT 11**

Project: ME-609
Country: USA
IND 58,500

Date	Serial #	To	Description
1998-11-18	N/A	DAVDP	Pre-IND submission notification
1998-11-24	N/A	DAVDP	Pre-IND documentation submission
1999-04-15	N/A	Medivir	FDA comments to pre-IND documentation
1999-06-18	000	DAVDP	Initial IND application and response to pre-IND comments
1999-07-09	N/A	Inveresk (US agent)	FDA acknowledgement of IND, assignment of IND # 58,500
1999-07-21	N/A	Inveresk	FDA fax. Clearance to proceed with clinical trial 98-609-003. Comments to inital IND application (clinical and CMC).
1999-08-06	001	DAVDP	Information amendment: Chemistry. Certificates of analysis for clinical supply batches.
1999-08-24	N/A	Inveresk	FDA letter. Same content as 21 July fax.
1999-09-17	N/A	Inveresk	FDA fax. Comments on Laser Doppler Velocimetry.
1999-11-16	002	DAVDP	Response to FDA request for information, addressing comments of July 21, Aug 24, Sep 17, 1999.
2000-04-06	003	DAVDP	Information amendment: Chemistry. Stability data for clinical supply batches
2000-04-29	004	DAVDP	Protocol amendment for clinical trial 98-609-003. Amendment 2 (dated April 13, 2000) to increase patient population.
2000-07-11	005	DAVDP	Information amendment: Chemistry. Modification in manufacturing process. Certificates of analysis for new clinical supply batches.
2000-07-13	006	DAVDP	Protocol amendment for clinical trial 98-609-003. Amendment 2 (revised June 22, 2000) to increase patient population.
2000-09-18	007	DAVDP	Response to FDA request for information. Additional responses to comments of July 21, Aug 24, Sep 17, 1999.
2000-09-20	008	DAVDP	Annual report. July 21, 1999 to July 20, 2000.
2001-08-17	009	DAVDP	General correspondence: Omnicare Clinical Research is new US agent
2001-08-21	009	DAVDP	Transfer of obligation. Letter from Omnicare.
2001-09-07	010	DAVDP	Information amendment, CMC. Hydrocortisone source both France and Kalamazoo
2001-09-12	011	DAVDP	Annual Report. July 21, 2000 to July 20, 2001
2002-09-16	012	DAVDP	Annual Report. July 21, 2001 to July 20, 2002
2003-09-04	013	DAVDP	Annual Report. July 21, 2002 to July 20, 2003
2004-02-13	014	DAVDP	Mary Holland is new US agent (fax + letter)
2004-02-16	015	DAVDP	Request for EOP2 meeting
2004-02-25	-	DAVDP	Phone call about current FDA project manager.

Date	Serial #	To	Description
2004-02-25	-	Medivir	Email. Address for desk copies.
2004-02-27	-	Medivir	Email. Questions about study reports to be submitted
2004-02-27	-	DAVDP	Email response to above questions.
2004-03-04	-	DAVDP	Phone call. Tentative information on EOP2 meeting date.
2004-03-05	016	DAVDP	Submission of non-clinical and clinical reports.
2004-03-08	-	Medivir	Phone call about status of report submission and request for fax with synopses and table of contents of clinical reports.
2004-03-08	-	DAVDP	Email about arrival of report submission.
2004-03-09	-	Medivir	Phone call. Confirmation on EOP2 meeting April 21
2004-03-09	-	Medivir	Written confirmation of EOP2 meeting on April 21.
2004-03-18	017	DAVDP	Briefing package for EOP2 meeting
2004-03-18	-	DAVDP	Seven desk copies of above package
2004-03-22	-	Medivir	Email confirming receipt of package and requesting electronic version of section 1.3
2004-03-25	-	DAVDP	Email submission of electronic version of section 1.3
2004-04-16	-	DAVDP	Email. Information about coming CMC updates and brief CMC section overview.
2004-04-16	-	Medivir	Email confirmation of receipt of CMC email.
2004-04-20	-	Medivir	Fax regarding April 21 meeting. Reclassification of meeting and main issues for discussion.
2004-04-30	-	DAVDP	Email submission of Medivir's meeting minutes
2004-05-17	-	Medivir	FDA record of April 21 meeting
2004-05-19	-	Medivir	Microbiology comments.
2004-09-08	018	DAVDP	Clinical development information package: Discussion of comparator arms
2004-09-18	019	DAVDP	Annual Report. July 21, 2003 to July 20, 2004.
2004-11-03		Medivir	Clinical comments to Sept 8 submission
2004-11-19	-	Medivir	Email response regarding internal discussions on jurisdiction of IND
2004-11-29	020	DAVDP	Request for telecon to discuss jurisdiction of IND
2004-12-08	-	DAVDP	Email correction of serial number for Nov 29 submission
2004-12-09	-	DAVDP	Email: Confirmation of information regarding decision that DAVDP will continue as lead division
2004-12-13	-	DAVDP	Email: Objectives for Dec 15 telecon
2004-12-15	-	-	Medivir internal meeting minutes from Dec 15 telecon
2005-01-28	021	DAVDP	Clinical development information package Request for telecon on clinical development plan
2005-02-11	-	Medivir	Scheduling of telecon for March 21
2005-02-18	-	DAVDP	Extra copies of clin dev information package
2005-03-11	-	J. Jenkins, Office of New Drugs	Request for designation of the lead review division
2005-03-18	-	Medivir	Clinical comments to SN 021, for March 23 meeting
2005-03-28	-	Medivir	Clinical comments (one single study)

Date	Serial #	To	Description
2005-04-04	-	DAVDP	Email with questions on content of March 28 memo
2005-04-08	-	DAVDP	Medivir summary of March 23 meeting
2005-04-15	023*	DAVDP	Major CMC amendment
**Serial #022 was inadvertently not used*			
2005-04-20	-	Medivir	FDA Record of March 23 meeting
2005-04-27	-	Medivir	Clinical statistical comments referring to April 26 telecon
2005-04-29	024	DAVDP	Medivir summary of April 26 telecon and response to FDA comments of April 27
2005-05-04	025	DAVDP	Request for End of Phase 2 Meeting
2005-05-04	026	DAVDP	Proposal for acyclovir susceptibility testing and safety study in immunocompromised
2005-05-10	-	Medivir	Clinical/statistical comments to Medivir April 29 submission (#024)
2005-05-13	027	DAVDP	Medivir summary of May 11 telecon
2005-05-18	-	Medivir	Confirmation of EOP2 meeting on July 6
2005-05-19	028	DAVDP	Phase 3 study synopsis and sample size calculations
2005-05-19	029	DAVDP	Supplementary reports (stability, in vitro release and mouse efficacy) that should have been in the April 15 submission (#023)
2005-06-02	-	Medivir	Chemistry comments to Medivir April 15 submission (#023)
2005-06-03	030	DAVDP	Clinical study report for dermal irritation study
2005-06-03	031	DAVDP	Briefing package for EOP2 meeting July 6
2005-06-03	-	DAVDP	Desk copies for submissions #026, 028, 030 and 031
2005-06-30	-	Medivir	Draft comments for July 6, 2005 meeting
2005-07-01	-	DAVDP	Email clarification on formulation and dermal safety
2005-07-01		Medivir	Comment on dermal irritation study
2005-07-08	-	Medivir	Comment on photosafety study requirements
2005-07-14	032	DAVDP	Medivir minutes from July 6 EOP2 meeting
2005-08-08	-	Medivir	Official minutes from July 6 EOP2 meeting
2005-09-15	033	DAVDP	Annual report for July 21, 2004 to July 20, 2005
2005-10-01	034	DAVDP	Response to comments regarding photosafety testing and dermal irritation study
2005-10-28	035	DAVDP	Draft Patient Diary Card (for pivotal phase 3 study) submitted for comments
2005-11-09	-	Medivir	DDDP comments on photosafety response (SN#034)
2005-12-05	036	DAVDP	Response to chemistry comments June 2, 2005
2005-12-22	037	DAVDP	Request for Special Protocol Assessment for clinical protocol 609-04
2006-01-13	038	DAVDP	Clinical protocol 609-06 (immunocompromised subjects) for comments
2006-01-13	039	DAVDP	Request for wider pH limits in drug product specification
2006-01-13	040	DAVDP	Final study report for dermal sensitization study (study no 604603)

Date	Serial #	To	Description
2006-01-13	-	Medivir	Acknowledgement of receipt of Special Protocol Assessement (SN#037, submitted Dec 22, 2005, received Dec 29, 2005
2006-01-26	-	Medivir	Chemistry comments to response submitted Dec 5, 2005 (SN#036)
2006-02-10	-	Medivir	Special Procotol Assessment - comments
2006-02-27	041	DAVDP	Pediatric Use Study (request for waiver for study in younger children) and request for Type A meeting
2006-03-02	-	Medivir	Chemistry comments to SN#037 – approval of wider pH limits
2006-03-07	-	Medivir	Clinical comments to SN#038 – study in immunocompromised subjects
2006-03-14	-	Medivir	Microbiology comments to SN#038 – study in immunocompromised subjects
2006-03-15	-	Medivir	Clinical comments to SN#040 (dermal sensitization study report) – comments on clinical development from DDDP
2006-03-16	-	Medivir	Schedule of telecon on May 11, 2006 to discuss request for waiver from pediatric studies in younger children (SN#041)
2006-03-17	042	DAVDP	Response to comments on protocol 609-04 (SPA) dated Feb 10, 2006.
2006-03-29	043	DAVDP	CMC information (acyclovir cream, vehicle cream, viscosity validation, stability protocol)
2006-04-06	044	DAVDP	Response to DDDP's clinical comments dated March 15, 2006
2006-04-06	045	DAVDP	Response to clinical and microbiology comments to protocol 609-06 (IC) dated March 7 and March 14, 2006.
2006-04-18	-	Medivir	Email response regarding patient diary card submitted October 28, 2005
2006-04-28	-	Medivir	Statistics comments to SN#042 - plan for reassessment of sample size
2006-05-05	046	DAVDP	Final protocol study 609-04 + transfer of obligations + updated IB
2006-05-09	-	Medivir	Clinical comments to SN#041 – pediatric studies
2006-05-16	-	Medivir	FDA minutes from May 11 telecon re pediatric studies
2006-05-17	-	Medivir	Microbiological comments to SN#045 – IC study 609-06
2006-05-19	047	DAVDP	Minutes from May 11 telecon and synopsis for study 609-07 (adolescent study)
2006-06-01	048	DAVDP	Revised plan for reassessment of sample size and minutes from May 2 telecon
2006-06-29	049	DAVDP	Response to clinical comments dated Nov 9, 2005 regarding photosafety studies
2006-06-29	050	DAVDP	Response to microbiology comments dated May 17, 2006 regarding clinical protocol 609-06 (IC)

Date	Serial #	To	Description
2006-06-29	051	DAVDP	Protocol amendment no. 1 + new investigator Study 609-04
2006-07-21	052	DAVDP	New investigators Study 609-04
2006-08-08	-	Medivir	DDDP clinical comments to SN#049 – photosafety
2006-08-18	053	DAVDP	Protocol amendment no. 2 + new investigators Study 609-04
2006-08-25	-	Medivir	Clinical comments to SN#048 - reassessment of sample size in study 609-04. Microbiology comments to SN#050 - PCR testing in study 609-06.
2006-09-18	054	DAVDP	Annual report 7/21/2005 – 7/20/2006
2006-09-18	055	DAVDP	New investigators Study 609-04
2006-09-18	056	DAVDP	Response to clinical comments dated August 8, 2006 – commitment to perform photosafety studies
2006-09-20	-	Medivir	Emailing request for track-changes version of protocol in submission #053
2006-09-29	057	DAVDP	Response to microbiology comments dated August 25, 2006 – PCR testing in study 609-06
2006-09-29	058	DAVDP	Response to clinical comments dated August 25, 2006 – reassessment of sample size in study 609-04
2006-09-29	059	DAVDP	Resubmission of Study 609-04 Protocol Amendment #2: Change in Protocol
2006-10-25	060	DAVDP	New Investigators for Study 609-04
2006-12-04	061	DAVDP	New Investigators for Study 609-04
2006-12-26	062	DAVDP	New Investigators for Study 609-04
2007-02-13	063	DAVDP	Clinical protocols KGL#6201 (phototoxicity) and KGL#6202 (photocontact allergenicity) for comments
2007-02-23	064	DAVDP	Response to Microbiology Comments related to Protocol 609-06 (IC)
2007-03-09		Medivir	Clinical comments from DDDP to SN#63 (phototoxicity and photocontact allergenicity)
2007-03-12	065	DAVDP	SAP for Study 609-04
2007-03-14	066	DAVDP	Final Clinical protocols KGL#6201 (phototoxicity) and KGL#6202 (photocontact allergenicity) + investigator information
2007-04-04		Medivir	Response to SN#064 on d-thymidine proposal
2007-04-14	067	DAVDP	Response to Microbiology Comments related to Protocol 609-06 (IC) on d-thymidine proposal
2007-04-23	068	DAVDP	Protocol Amendment No. 3. Study 609-04
2007-05-01		Medivir	Statistical comments to SN#065 on SAP
2007-06-12	069	DAVDP	Protocol Amendment No. 4. Study 609-04
2007-06-12	070	DAVDP	Revised SAP (Version 3.1) for study 609-04 and response to FDA comments from May 1
2007-06-21		Medivir	Response to SN#064 on d-thymidine proposal
2007-07-24		Medivir	Statistical comments to SN#070 on revised SAP
2007-08-01	071	DAVDP	New Investigators for Study 609-04
2007-08-08	072	DAVDP	New Investigator for Study 609-04

Date	Serial #	To	Description
2007-09-07	073	DAVDP	Pre-NDA Meeting Request General/Nonclinical/Clinical
2007-09-10	074	DAVDP	Pre-NDA Meeting Request CMC
2007-09-14	-	Medivir	CMC meeting granted by FDA
2007-09-19	075	DAVDP	Annual Report for period 21/7-2006 to 20/7-2007
2007-09-21	-	Medivir	General/nonclinical/clinical meeting granted by FDA
2007-09-25	076	DAVDP	Study KGL6020 – Protocol Amendment 1: Challenge phase with individual ingredients
2007-10-03	077	DAVDP	Protocol Amendment No. 5. Study 609-04
2007-10-10	078	DAVDP	CMC Pre-NDA Meeting Package
2007-10-12	079	DAVDP	General/Nonclinical/Clinical Pre-NDA Meeting Package
2007-10-30	080	DAVDP	New Investigator Study 609-04
2007-11-07		Medivir	FDA comments on SN#079 Pre-NDA meeting package
2007-11-08		Medivir	FDA comments on SN#078 CMC Pre-NDA meeting package
2007-11-09		Medivir	FDA comments on SN#076 Study KGL6202
2007-12-04	081	DAVDP	Response to Clinical Comments - Clinical Study Protocol KGL #6202, Amendment 1
2007-12-13		Medivir	FDA official minutes from CMC Pre-NDA meeting
2007-12-20	082	DAVDP	Response to statistical comments. SAP version 3.2
2007-12-21	083	DAVDP	CMC pre-NDA Meeting – Sponsor meeting minutes
2008-02-13		Medivir	ROC with FDA office of Generics re. Inactive Ingredients Limits (Poloxamer 188; Isopropyl Myristate)
2008-02-14	084	DAVDP	CMC: in vitro release data and homogeneity data for evaluation
2008-03-06	085	DAVDP	Pre-NDA Meeting Request General/Nonclinical/Clinical
2008-04-23	086	DAVDP	Pre-NDA Meeting Briefing Package
2008-03-27		Medivir	General/nonclinical/clinical meeting granted by FDA on May 22
2008-05-05		Medivir	FDA clinical comments to SN#085, request for further information
2008-05-09	087	DAVDP	Response to FDA clinical comments from May 5
2008-05-15		Medivir	FDA contact re Pre-NDA meeting (e-mail)
2008-05-19		Medivir	FDA Pre-NDA meeting responses
2008-05-21	088	DAVDP	Response to FDA Request: Correction to pre-NDA Meeting Briefing Package
2008-06-03	089	DAVDP	Response to FDA request for Information on study sites on study 609-04
2008-06-12	090	DAVDP/ DDDP	Teleconference request and briefing package (Citric acid content)
2008-06-13	091	DAVDP	Sponsor Pre-NDA meeting minutes
2008-06-17		Medivir	FDA response to SN#084, homogeneity data
2008-06-24		Medivir	FDA official Meeting minutes Pre-NDA meeting

Date	Serial #	To	Description
2008-06-25	092	DAVDP	Response to FDA comments
2008-06-30		Medivir	FDA response to SN#90, cancellation of teleconference
2008-07-11	093	DAVDP	Request for clarification/Revision to FDA issued pre-NDA Meeting Minutes
2008-07-11		FDA	Request for Small Business Waiver of the New Drug Application Fee
2008-07-30	094	DAVDP	Request for Review of Sample SAS Transport File Format
2008-08-11	095	DAVDP	CMC information amendment: Appearance Specification and Microscopic Method
2008-08-28		Medivir	SAS file comments
2008-09-16	096	DAVDP	Annual Report July 2007-July 2008

NDA Regulatory correspondence log

Project: ME-609
Country: USA
NDA 22-436

Date	Serial #	To	Description
2008-09-29	0000	DAVDP	505(b)2 NDA submission
2008-10-27	mail	DAVDP	Clarification of location of clinical data
2008-10-28	0001	DAVDP	Request for Trade name review
2008-10-30	0002	DAVDP	Addendum study 609-06: 12 month follow-up data
2008-11-07	mail	Medivir	Request from Division of Scientific Investigations (DSI)
2008-11-14		DSI	Study 609-04: Site specific information
2008-11-19	0003	DAVDP	Updated User Fee Cover Sheet
2008-12-05	0004	DAVDP	Updated form FDA 356h
2008-12-15		DSI	Site specific CRFs for 609-04
2008-12-23	0005	DAVDP	Response to filing communication
2009-01-08	Fax	Medivir	ROC 07: Letter re. Small Business waiver
2009-03-19	Fax	Medivir	ROC 08: Clinical comments re inspection of site 17
2009-03-19	Fax	Medivir	ROC 09: Clinical Pharmacology Comments
2009-04-03	Fax	Medivir	ROC 10: Submit draft ped. Study synopsis. Comments on studies 604598 and 604603
2009-04-16	0006	DAVDP	Response to clinical comments and comments from DDDP
2009-04- 17	Mail	Medivir	ROC 11: regarding submission 0006 (mail)
2009-04-17	0007	DAVDP	Response to clinical site investigation comments (March 19)
2009-04-20	0008	DAVDP	Paediatric plan
2009-04-21		Medivir	ROC 12: FDA wants more specific date for Paed study
2009-04-23		Medivir	ROC13: Statistics comments on ME-609-06
2009-04-23	0009	DAVDP	Updated paediatric study plan
2009-04-30	0010	DAVDP	Response to Clinical Pharmacology Questions (March 19)
2009-05-04		Medivir	ROC 14: Proposed tradename unacceptable
2009-05-07	Fax	Medivir	ROC 15: Annual user fees (no fees are due)
2009-05-08	0011	DAVDP	Response to Statistics Comments (April 23)
2009-06-03	0012	DAVDP	Final Clinical Study Report 609-06
2009-06-03		Medivir	ROC 16: trade name review
2009-06-10		Medivir	ROC 17: Label and Tube Example
2009-06-16		Medivir	ROC 18: Clarification from David Araojo
2009-06-24		Medivir	ROC 19: Additional Label revisions from DDDP
2009-06-29	0013	DAVDP	Response to labeling Comments/Revisions
2009-07-02		Medivir	ROC 20: Label comments microbiology
2009-07-02		Medivir	ROC 21: Attachment
2009-07-15	0014	DAVDP	Response to Labeling Comments (Microbiology – 02 July 2009)
2009-07-20		Medivir	ROC 23: CMC Comments

Date	Serial #	To	Description
2009-07-23		Medivir	ROC 24: Chemistry comments
2009-07-27		Medivir	ROC 25: Label revision
2009-07-27	0015	DAVDP	Response to Information request letter (20 July 2009) and Request for Labeling Revisions (27 July 2009)
2009-07-31		Medivir	FDA APPROVAL LETTER